The Honorable Robert S. Lasnik

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, *et al.*, *ex rel.* SCEF, LLC, *et al.*,

Plaintiffs,

v.

ASTRAZENECA PLC, *et al.*,

Defendants.

No. 2:17-cv-01328-RSL

SUPPLEMENTAL DECLARATION OF JOHN MININNO IN SUPPORT OF RELATORS' RESPONSE TO UNITED STATES' MOTION TO DISMISS RELATORS' COMPLAINT

I, John Mininno, declare as follows:

I make this supplemental declaration in support of the Relators' Response to United States' Motion to Dismiss Relators' Complaint, Dkt. # 34, and to respond to certain arguments raised in the Reply Memorandum in Support of the United States' Motion to Dismiss Relators' Complaint ("Reply"), Dkt. # 39.

1. I have personal knowledge of the matters stated herein and if called upon to testify as to them I could and would do so competently.

2. I am a member of Venari Partners, LLC, which does business as the National HealthCare Analysis Group ("NHCA"). NHCA is the managing member of Relator SCEF, LLC.

3. The Reply asserts that "[t]he notion that NHCA Group had no preconception that the information it collected from former employees in 'surveys' would be used for litigation strains credulity." Dkt. # 39 at p. 4. While it is true that some of NHCA's qualitative findings were eventually later used to support the allegations in these matters, NHCA could never fully know in advance what it would learn from its research interviews—this is quite standard in any kind of research. Consistent with qualitative research principles and norms, and consistent with NHCA's own mission, participants were treated with respect, beneficence, and justice; and interviewers' biases, if any, remained private. Still, key here is that the vast majority of the NHCA's day-to-day activity over the last five years was *never* used in any litigation; instead, the information gained from the research was used to increase the NHCA's domain expertise in the field of the detection and prevention of fraud, waste, and abuse in the healthcare industry. The industry constantly changes over time and in order to maintain domain expertise, the qualitative research is an ongoing process.

4. The Reply states: "[s]everal witnesses were solicited for NHCA Group's 'qualitative research study' *after* NHCA Group had already filed actions in Massachusetts, New York, and Texas alleging substantially the same conduct, including against one of the same defendants in this case. Worse yet, two witnesses in this case appear to have been interviewed for this case *after* it had been filed, and yet NHCA Group persisted with the pretext of 'qualitative research' and emphasized its claim of 'no bias one way or the other about the industry.'" Dkt. # 39 at p. 4. AstraZeneca is not a defendant in the Massachusetts, New York, or Texas actions. While some of the nurse educator placement agencies overlap in the cases, the claims of each case necessarily flow from the actions of the pharmaceutical companies and, in this case, the particular actions taken by AstraZeneca defendants. Further, the two witnesses interviewed in

this case after it was filed were both Bydureon witnesses. Both witnesses were originally interviewed prior to the filing of the Complaint and had their facts included in the Complaint. The primary purpose of the follow-up interviews with these individuals was to obtain the names of prescribing physicians with whom they worked regarding Bydureon so that the prescription data for the physicians could be provided to the United States of America ("Government").

5. The Government continues to assail my research methodology. *See* Dkt. # 39 at 4 n.4. However, we have used qualitative and investigatory research principles in all of our cases, *i.e.*, the evidence NHCA provided in other cases was not based on double-blind research. For example, NHCA did not use double-blind research when we appeared as relator PRAPOMA, LLC in *United States ex rel. Doe v. Insys Therapeutics, Inc.*, No. 14-3488 (C.D. Cal.), a case in which the United States intervened and utilized my research without raising any concerns about my investigative techniques or methodology. The Government states that the first to file Novo Nordisk settlement captioned *United States ex rel. Kennedy v. Novo A/S*, No. 13-1529 (D.D.C.), did not resolve any white coat marketing or Anti-Kickback Statute claims of any sort. Dkt. # 39 at p. 5. They are technically correct in that assertion. However, the conduct that was settled involved, *inter alia*, unlawful drug promotion by both Novo sales reps and Certified Diabetes Educators (or nurses)—which we refer to as White Coat Marketing.

6. Since we were not first to file, we did not share in that reward. However, in its press release, the United States Department of Justice referenced our case and all the others that contributed to this outcome:

> The FCA settlement *resolves* seven lawsuits filed under the whistleblower provision of the federal FCA, which permits private parties to file suit on behalf of the United States for false claims and share in a portion of the government's recovery. The civil lawsuits are captioned as follows: *United States, et al. ex rel. Kennedy, v. Novo A/S, et al.*, No. 13-cv-01529 (D.D.C.), *United States, et al. ex rel. Dastous, et al. v. Novo Nordisk*, No. 11-cv-01662 (D.D.C), *United States, et*

al., ex rel. Ferrara and Kelling v Novo Nordisk, Inc., et al., No. 1:11-cv-00074 (D.D.C.), *United States, et al., ex rel. Myers v. Novo Nordisk, Inc.*, No. 11-cv-1596 (D.D.C.), *United States, et al. ex rel. Stepe v. Novo Nordisk, Inc.*, No. 13-cv-221 (D.D.C.), ***United States et al. ex rel. Doe, et al. v. Novo Nordisk, Inc., et al.*, No. 1:17-00791 (D.D.C.)**, and *United States ex rel. Smith, et al. v. Novo Nordisk, Inc.*, Civ. Action No. 16-1605 (D.D.C.).

Novo Nordisk Agrees to Pay $58 Million for Failure to Comply with FDA-Mandated Risk Program, Dep't of Just. (Sept. 5, 2017), https://www.justice.gov/opa/pr/novo-nordisk-agrees-pay-58-million-failure-comply-fda-mandated-risk-program (emphasis added). A true and correct copy of the press release is attached as Exhibit 1.

7. The Reply also provides a recitation of the "extensive discussions" that the government had with "NHCA Group counsel." Dkt. # 39 at p. 7. However, other than one initial call with the Government in which Relators' counsel from this case participated and the general theories raised in the collective cases were discussed, all of the other calls and meetings referenced in the Reply and the Government's declarations focused on the particular facts of the cases NHCA brought in Texas.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 30thday of September 2019, in Burlington County, New Jersey.

John Mininno

EXHIBIT 1

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, September 5, 2017

Novo Nordisk Agrees to Pay $58 Million for Failure to Comply with FDA-Mandated Risk Program

Payments Resolve Allegations Highlighted in DOJ Civil Complaint and Recently Unsealed Whistleblower Actions

Pharmaceutical Manufacturer Novo Nordisk Inc. will pay $58.65 million to resolve allegations that the company failed to comply with the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) for its Type II diabetes medication Victoza, the Justice Department announced today. The resolution includes disgorgement of $12.15 million for alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA) from 2010 to 2012 and a payment of $46.5 million for alleged violations of the False Claims Act (FCA) from 2010 to 2014. Novo Nordisk is a subsidiary of Novo Nordisk U.S. Holdings Inc., which is a subsidiary of Novo Nordisk A/S of Denmark. Novo Nordisk's U.S. headquarters is in Plainsboro, New Jersey.

"Today's resolution demonstrates the Department of Justice's continued commitment to ensuring that drug manufacturers comply with the law," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "When a drug manufacturer fails to share accurate risk information with doctors and patients, it deprives physicians of information vital to medical decision-making."

In a civil complaint filed today in the U.S. District Court for the District of Columbia asserting claims under the FDCA, the government alleged that, at the time of Victoza's approval in 2010, the Food and Drug Administration (FDA) required a REMS to mitigate the potential risk in humans of a rare form of cancer called Medullary Thyroid Carcinoma (MTC) associated with the drug. The REMS required Novo Nordisk to provide information regarding Victoza's potential risk of MTC to physicians. A manufacturer that fails to comply with the requirements of the REMS, including requirements to communicate accurate risk information, renders the drug misbranded under the law.

As alleged in the complaint, some Novo Nordisk sales representatives gave information to physicians that created the false or misleading impression that the Victoza REMS-required message was erroneous, irrelevant, or unimportant. The complaint further alleges that Novo Nordisk failed to comply with the REMS by creating the false or misleading impression about the Victoza REMS-required risk message that violated provisions of the FDCA and led some physicians to be unaware of the potential risks when prescribing Victoza.

As alleged in the government's complaint, after a survey in 2011 showed that half of primary care doctors polled were unaware of the potential risk of MTC associated with the drug, the FDA required a modification to the REMS to increase awareness of the potential risk. Rather than appropriately implementing the modification, the complaint alleges that Novo Nordisk instructed its sales force to provide statements to doctors that obscured the risk information and failed to comply with the REMS modification. Novo Nordisk has agreed to disgorge $12.15 million in profits derived from its unlawful conduct in violation of the FDCA.

"Novo Nordisk's actions unnecessarily put vulnerable patients at risk," said U.S. Attorney Channing D. Phillips for the District of Columbia. "We are committed to holding companies accountable for violating the integrity of the FDA's efforts to ensure that doctors and patients have accurate information that allows them to make appropriate decisions about which drugs to use in their care. Working with the FDA and other law enforcement partners, we have sent a strong signal to the drug industry today."

"Novo Nordisk Inc. sales representatives misled physicians by failing to accurately disclose a potential life threatening side effect of a prescription drug, and needlessly increased risks to patients being treated with this drug," said Assistant Director in Charge Andrew W. Vale of the FBI's Washington Field Office. "The FBI is committed to ensuring that the private industry provides honest and accurate risk information to the public and will continue to work closely with our law enforcement partners to investigate companies who do not comply with FDA-mandated policies."

"We need to trust that pharmaceutical companies truthfully represent their products' potential risks," said Special Agent in Charge Nick DiGiulio for the U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG). "We will continue to work with our partners to ensure federal health care dollars are spent only on drugs that are marketed honestly."

Novo Nordisk will pay an additional $46.5 million to the federal government and the states to resolve claims under the FCA and state false claims acts. This portion of the settlement resolves allegations that Novo Nordisk caused the submission of false claims from 2010 to 2014 to federal health care programs for Victoza by arming its sales force with messages that could create a false or misleading impression with physicians that the Victoza REMS-required message about the potential risk of MTC associated with Victoza was erroneous, irrelevant, or unimportant and by encouraging the sale to and use of Victoza by adult patients who did not have Type II diabetes. The Food and Drug Administration (FDA) has not approved Victoza as safe and effective for use by adult patients who do not have Type II diabetes.

As a result of today's FCA settlement, the federal government will receive $43,129,026 and state Medicaid programs will receive $3,320,963. The Medicaid program is funded jointly by the state and federal governments.

The FCA settlement resolves seven lawsuits filed under the whistleblower provision of the federal FCA, which permits private parties to file suit on behalf of the United States for false claims and share in a portion of the government's recovery. The civil lawsuits are captioned as follows: *United States, et al. ex rel. Kennedy, v. Novo A/S, et al*., No. 13-cv-01529 (D.D.C.), *United States, et al. ex rel. Dastous, et al. v. Novo Nordisk*, No. 11-cv-01662 (D.D.C), *United States, et al., ex rel. Ferrara and Kelling v Novo Nordisk, Inc., et al*., No. 1:11-cv-00074 (D.D.C.), *United States, et al., ex rel. Myers v. Novo Nordisk, Inc.,* No. 11-cv-1596 (D.D.C.), *United States, et al. ex rel Stepe v. Novo Nordisk, Inc.,* No. 13-cv-221 (D.D.C.), *United States et al. ex rel Doe, et al. v. Novo Nordisk, Inc.*, et al., No. 1:17-00791 (D.D.C.), and *United States ex rel. Smith, et al. v. Novo Nordisk, Inc.*, Civ. Action No. 16-1605 (D.D.C.). The amount to be recovered by the private parties has not been determined.

The settlements were the result of a coordinated effort among the U.S. Attorney's Office for the District of Columbia and the Civil Division's Consumer Protection Branch and Commercial Litigation Branch, with assistance from the FDA's Office of Chief Counsel. The investigation was conducted by the FDA's Office of Criminal Investigations, the FBI, HHS-OIG, the Defense Criminal Investigative Service and the Office of Personnel Management, Office of the Inspector General.

For more information about the Consumer Protection Branch and its enforcement efforts, visit its website at http://www.justice.gov/civil/consumer-protection-branch. For more information on the Commercial Litigation Branch's Fraud Section, visit https://www.justice.gov/civil/fraud-section. For more information about the U.S. Attorney's Office for the District of Columbia, visit https://www.justice.gov/usao-dc.

Attachment(s):
Download Novo Nordisk Complaint
Download Novo Nordisk Executed FDCA Settlement

Topic(s):
False Claims Act
Health Care Fraud

Component(s):
Civil Division

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17-968

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